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14. ABSTRACT

Therapeutics, Inc. 1) wrote and gained approval for the data safety monitoring plan for this protocol; 2) identified and contracted a medical monitor for this protocol; 3) revised the protocol, informed consent and case report forms, and obtained approval by the USAMRMC ORP HRPO; 4) submitted the protocol and informed consent form to the Western IRB for approval; 5) is collaborating with Windber Research Institute in the preparation of the protocol for the gene chip analysis; 6) secured the vendor for the specimen kits; and negotiated a contract with vendor to provide the electronic data collection, management, and reporting system used for this protocol; and, 7) contracted a medical science liaison for the identification of qualified participating investigators and sites.

15. SUBJECT TERMS
ChemoFX Chemoresponse Assay, Breast Cancer, Prediction of Response

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Introduction

The objective of this study is to develop a biomarker to predict pathological complete response in women treated with neoadjuvant chemotherapy for breast cancer. Such a biomarker would assist physicians in selecting the most effective chemotherapy for the individual patient. The anticipated biomarker will take into account clinical factors (such as tumor stage, tumor size, and age), phenotypic characteristics of the tumor (determined by pathological immunohistochemistry and *ex vivo* chemoresponse assay), and genotypic characteristics of the tumor and patient (determined by genomic profiling via gene expression analysis of tumor RNA). It is expected that collective consideration of all of these factors will be more predictive of patient response to therapy than any of them alone.

Approximately 224 evaluable subjects will be recruited from approximately 1 to 10 US sites. Women with palpable operable invasive breast cancer diagnosed by core needle biopsy will be eligible for this study. Additional tumor specimens will be obtained prior to the start of chemotherapy via core needle biopsies to be used in the *ex vivo* chemoresponse assay and tumor genomic analysis (gene expression), respectively.

All subjects will receive neoadjuvant chemotherapy at the discretion of their physician using non-investigational chemotherapy agents (see NCCN guidelines).[1] Upon completion of chemotherapy treatment, women will undergo lumpectomy, modified radical mastectomy or other surgical procedure determined appropriate by the investigator to evaluate pathological response. The treating physician will remain blinded to the results of the chemoresponse assay and genomic analysis.

Body

PT-304 has not opened to accrual and there are no patients enrolled on the study.

Progress to date includes the following by Precision Therapeutics, Inc.:

- Wrote and gained approval for the data safety monitoring plan for this protocol.
- Identified and contracted a medical monitor for this protocol; Ruth O'Regan, MD, Director of Clinical and Translational Breast Cancer at Emory University School of Medicine, Winship Cancer Institute.
- Revised the protocol, informed consent and case report forms, and obtained approval by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO).
- Submitted the protocol and informed consent form to the Western IRB for approval (approval pending).
- Currently collaborating with Windber Research Institute for the preparation of the protocol for the gene chip analysis.
- Secured the vendor for the specimen kits; Therapak.

- Negotiated a contract with MedNet Solutions Inc. to provide the electronic data collection, management, and reporting system used for this protocol.

- Contracted a medical science liaison for the identification of qualified participating investigators and sites.

Key Research Accomplishments

Not applicable

Reportable Outcomes

Not applicable

Conclusion

Not applicable

References

Not applicable

Appendices

Not applicable

Supporting Data

Not applicable